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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,489	06/23/2003	Ian David Manger	F131.K1.US	1122

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FLUIDIGM CORPORATION
7100 SHORELINE COURT
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,489	MANGER ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-13,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a microfluidic device comprising intersecting channels and valves, classified in class 422, subclass 100.

II. Claims 14-31, drawn to a method of conducting a binding assay, classified in class 436, subclass 501.

III. Claims 32 and 33, drawn to a method for producing a microfluidic device, classified in class 422, subclass 100.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the microfluidic device can be used to meter and control the movement of fluids rather than being used to conduct binding assays.

Inventions (I and II) and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the elastomeric layer of the microfluidic device of Groups I and II can comprise a single layer instead of three separate layers.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with William Smith on 06/06/06 a provisional election was made with the preservation of traverse to prosecute the invention of Group II, claims 14-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13, 32 and 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The different combinations of the two binding ligands recited in the claim must be recited in the alternative. Claim 14 recites only a single reagent and a single sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **14-16, 18-22, 28-30** are rejected under 35 U.S.C. 102(e) as being anticipated by Van Dam et al. (US 2003/0008411 A1).

Van Dam et al. disclose a microfluidic device and a method for synthesizing a library of compounds by using the microfluidic device (see claim 15), which includes DNA synthesis (see [0056]). The device comprises a solid substrate layer and an elastomeric layer attached to the solid substrate wherein the surface of the solid substrate bonded to the elastomeric layer is adapted to bind ligands of interest. The surfaces of both layers can comprise grooves/wells to define a plurality of first flow channels intersecting a plurality of second flow channels (see claim 24 and [0048]). The device further comprises a plurality of control channels associated with each of the flow channels. Upon the application of an actuation force within the control channels, the surface of the control channels deflect into the flow channels and block fluid flow through the flow channels. The control channels also act as a pump for facilitating the movement of fluids through the flow channels (see [0068] and [0069]).

The method comprises the steps of introducing a reagent comprising a ligand into the first flow channels such that the ligands bind to the surface of the solid substrate, and then introducing a sample solution into the second flow channels such that the sample in the sample solution circulates through the flow channels and binds the ligands bound to the substrate (see claims 25 and 26). The reference discloses that while fluid is being introduced into one of the two flow channels, the other set of flow channels is closed off by means of the control valves in order to prevent cross-contamination (see [0089]). The reference also discloses that ligands that do not bind to the substrate are rinsed off using a solvent (see [0084]). The reference discloses that the limitation "reagent" refers to oligonucleotides, peptides, monomers, and other small molecules that are building blocks of a larger molecule (see [0056]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **17, 23-26 and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Dam et al.

Van Dam et al. does not explicitly disclose 1) actuating all the control valves to allow the reagent and the sample to incubate; 2) the usage of a detector to observe the compound synthesis; or 3) conducting an assay involving antimicrobes.

Although the Van Dam et al. reference does not explicitly disclose the step of actuating all the valves in order to allow the reagent and the sample to thoroughly react, it is well-known in the art to allow reactions to incubate, especially for synthesis reactions such as PCR. It would have been obvious to one of ordinary skill in the art to actuate all the valves after the introduction of the sample in the method disclosed by Van Dam et al. so that the reaction between the reagent and the sample can thoroughly proceed.

Although the Van Dam et al. reference does not explicitly disclose the step of using a detector to observe the reaction product, the reference does disclose the step of derivatizing the solid substrate and determining the efficacy of the derivatization (see [0122]). This is accomplished by derivatizing the surface of the solid substrate with functional groups adapted to bind the reagent and reacting fluorophores with the functional groups and detecting the fluorescence. In light of the disclosure, it would have been obvious to one of ordinary skill in the art to tag the synthesized compounds produced by the method disclosed by Van Dam et al. and detect the fluorescence using a fluorescent microscope in order to observe the efficacy of the synthesis.

Although the Van Dam et al. reference does not explicitly disclose an assay involving antimicrobes, given that the device disclosed by the Van Dam reference is adapted to perform an assay (bind one ligand to another ligand), it would have been obvious to one of ordinary skill in the art to react any two entities that bind using the device disclosed by Van Dam et al., including a cell as the reagent and antimicrobes as the sample in order to observe the effects of the antimicrobes on the cell.

Claim **27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Dam et al. in view of Raillard et al. (US 2002/0102577 A1).

Van Dam et al. does not explicitly disclose the usage of a non-optical detector to observe the compound synthesis. However, the Van Dam et al. reference discloses the step of derivatizing the solid substrate and determining the efficacy of the derivatization (see [0122]). This is accomplished by reacting fluorophores with the functional groups that are attached to the solid substrate and detecting the fluorescence.

Raillard et al. disclose a method for labeling probes with radio-isotopes that emit radiation (see [0132]). The probe is detected using a detector that is sensitive to radiation.

In light of the disclosure of both Van Dam et al. and Raillard et al., it would have been obvious to one of ordinary skill in the art to tag the synthesized compounds produced by the method disclosed by Van Dam et al. with radio-isotope probes and detect the radiation using a detector in order to observe the efficacy of the synthesis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,508,988 B1 discloses a microfluidic device and a method for synthesizing a library of compounds by using the microfluidic device. The device comprises a solid substrate layer and an elastomeric layer attached to the solid substrate wherein the surface of the solid substrate bonded to the elastomeric layer is adapted to bind ligands of interest. The layers together define a plurality of first flow channels intersecting a

plurality of second flow channels. The device further comprises a plurality of control channels associated with each of the flow channels. Upon the application of an actuation force within the control channels, the surface of the control channels deflect into the flow channels and block fluid flow through the flow channels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
08/04/06

Jill Warden
Supervisory Patent Examiner
Technology Center 1700